federal register

MONDAY, OCTOBER 15, 1973
WASHINGTON, D.C.

Volume 38 ■ Number 198

PART III

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

RADIOLOGICAL HEALTH

Reorganization and Republication

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Recodification Docket No. 1]

SUBCHAPTER J—RADIOLOGICAL HEALTH

REORGANIZATION AND REPUBLICATION

The Commissioner of Food and Drugs, for the purpose of establishing an orderly development of informative regulations for the Food and Drug Administration, furnishing ample room for expansion of such regulations in years ahead, and providing the public and affected industries with regulations that are easy to find, read, and understand, has initiated a recodification program for Chapter I of Title 21 of the Code of Federal Regulations. This is the first document in a series of recodification documents that will eventually include all regulations administered by the Food and Drug Administration.

The regulations formerly under Part 278—Regulations for the Administration and Enforcement of the Radiation Control for Health and Safety Act of 1968 have been reorganized into eight parts in an effort to provide greater clarity and adequate space for the development of future regulations.

The changes being made are nonsubstantive in nature and for this reason notice and public procedure are not prerequisites to this promulgation. For the convenience of the user the entire text of the revised Subchapter J—Radiological Health is set forth below.

Dated October 5, 1973.

SAM D. FINE,
Associate Commissioner for Compliance.

Therefore, Part 278 of Chapter I, Subchapter F, is redesignated as Subchapter J consisting of Parts 1000–1030 and republished to read as set forth below.

SUBCHAPTER J—RADIOLOGICAL HEALTH

Parts

1000 General.
1002 Records and Reports.
1003 Notification of Defects or Failure to Comply.
1004 Repurchase, Repairs or Replacement of Electronic Products.
1005 Importation of Electronic Products.
1010 Performance Standards for Electronic Products: General.
1020 Performance Standards for Ionizing Radiation Emitting Products.
1030 Performance Standards for Microwave and Radio Frequency Emitting Products.

PART 1000—GENERAL

Subpart A—General Provisions

Sec.

1000.3 Definitions.

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1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

AUTHORITY: Secs. 215, 356, 58 Stat. 690, 82 Stat. 1174; 42 U.S.C. 216, 263d.

Subpart A—General Provisions

§ 1000.3 Definitions.

As used in this Subchapter J:

(a) "Electronic product radiation" means—

(1) Any ionizing or nonionizing electromagnetic or particulate radiation, or

(2) Any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product.

(b) "Electromagnetic radiation" includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, X-rays, ultraviolet, visible, infrared, microwave, radiowave, and low frequency radiations.

(c) "Particulate radiation" is defined as charged particles such as protons, electrons, alpha particles, heavy particles, etc., which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions or electrical repulsion or uncharged particles such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation by collision.

(d) "Infrasonic, sonic (or audible) and ultrasonic waves" refer to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid or solid) that can be detected by an instrument or listener.

(e) "Electronic product" means (1) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (2) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in subparagraph (1) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation.

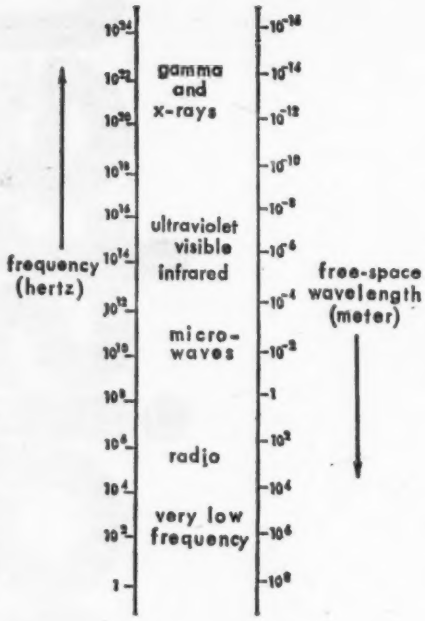

Figure 1. The Electromagnetic Spectrum

(f) "Manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products.

(g) "Commerce" means (1) commerce between any place in any State and any place outside thereof, and (2) commerce wholly within the District of Columbia.

(h) "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

(i) "Act" means the Radiation Control for Health and Safety Act of 1968 (Public Law 90–602, 42 U.S.C. 263b et seq.).

(j) "Secretary" means the Secretary of the Department of Health, Education, and Welfare.

(k) "Federal standard" means a performance standard issued pursuant to section 358 of the Act.

(l) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(m) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(n) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic

product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(o) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

Subpart B—Statements of Policy and Interpretation

§ 1000.15 Examples of electronic products subject to the Radiation Control for Health and Safety Act of 1968.

The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which the regulations of this part apply.

(a) Examples of electronic products which may emit X-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

Ionizing electromagnetic radiation:
- Television receivers.
- Accelerators.
- X-ray machines (industrial, medical, research, educational).

Particulate radiation and ionizing electromagnetic radiation:
- Electron microscopes.
- Neutron generators.

(b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio and low frequency electromagnetic radiation include:

Ultraviolet:
- Biochemical and medical analyzers.
- Tanning and therapeutic lamps.
- Sanitizing and sterilizing devices.
- Black light sources.
- Welding equipment.

Visible:
- White light devices.

Infrared:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.

Microwave:
- Alarm systems.
- Diathermy units.
- Dryers, ovens, and heaters.
- Medico-biological heaters.
- Microwave power generating devices.
- Radar devices.
- Remote control devices.
- Signal generators.

Radio and low frequency:
- Cauterizers.
- Diathermy units.
- Power generation and transmission equipment.
- Signal generators.
- Electromedical equipment.

(c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:

Laser:
- Art-form, experimental and educational devices.
- Biomedical analyzers.
- Cauterizing, burning and welding devices.
- Cutting and drilling devices.
- Communications transmitters.
- Rangefinding devices.

Maser:
- Communications transmitters.

(d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit include:

Infrasonic:
- Vibrators.

Sonic:
- Electronic oscillators.
- Sound amplification equipment.

Ultrasonic:
- Cauterizers.
- Cell and tissue disintegrators.
- Cleaners.
- Diagnostic and nondestructive testing equipment.
- Ranging and detection equipment.

PART 1002—RECORDS AND REPORTS

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Subpart G—Codes for Reporting Listed Electronic Products

1002.61 List of specific product groups.

AUTHORITY: Sec. 360A, 82 Stat. 1182; 42 U.S.C. 2631.

Subpart A—General Provisions

§ 1002.1 Applicability.

The provisions of this part are applicable to manufacturers, dealers, and distributors of electronic products as specified herein, but, except for § 1002.20, are not applicable to:

(a) Manufacturers of electronic products intended solely for export if such a product is labeled or tagged to show that the product is intended for export, and the product meets all the applicable requirements of the country to which such product is intended for export, and

(b) Manufacturers of listed products sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers.

(c) Manufacturers of electronic products which are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification.

§ 1002.2 Definitions.

As used in this part:

(a) The term "dealer" means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business, and includes persons who offer such products for lease or as prizes or awards.

(b) The term "distributor" means a person engaged in the business of offering electronic products for sale to dealers without regard to whether such person is or has been primarily or customarily engaged in such business.

(c) The term "purchaser" means the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and also includes a person who leases an electronic product for purposes other than subleasing.

(d) The term "accidental radiation occurrence" means a single event or series of events occurring in the course of the manufacturing, testing, or use of any electronic product which has resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a direct result of the manufacturing, testing, or use of that product.

(e) The term "model" means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

§ 1002.3 Records and reports on components.

Records and reports required for products listed in § 1002.61 shall include information on all components which the manufacturer may provide with the listed product and which affect the quantity, quality, or direction of the radiation emissions.

§ 1002.4 Confidentiality of information.

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to this part, which concerns or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

Subpart B—Required Manufacturers' Reports for Listed Electronic Products

§ 1002.10 Initial reports.

Every manufacturer of a product listed under § 1002.61, shall submit an initial report to the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852, in accordance with this section. The report shall be submitted within 90 days following the effective date of this subpart or prior to the introduction of such product into commerce, whichever is later. The report shall be distinctly marked "Initial Report of (Name of Manufacturer)" and shall:

(a) State in the report for each model of a listed product whether the report is submitted pursuant to paragraph (a), (b), or (c) of § 1002.61.

(b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling sufficient to enable the Secretary to determine the date and place of manufacture.

(c) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product.

(d) State the standards or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a Federal standard, if applicable.

(e) For each model, describe the physical or electrical characteristics such as shielding, or electronic circuitry, etc., incorporated into the product in order that the standards or specifications reported pursuant to paragraph (d) of this section are met.

(f) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures.

(g) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary.

(h) Provide sufficient results of the testing and measuring of electronic product radiation safety and of the quality control procedures described in accordance with paragraphs (f) and (g) of this section to enable the Secretary to determine the effectiveness of the methods and procedures used to accomplish the stated purposes.

(i) Report for each model, all warning signs, labels and instructions, for installation, operation, and use which relate to electronic product radiation safety.

(j) Provide upon request such other information as the Secretary may reasonably require to enable him to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Secretary to carry out the purposes of the Act.

§ 1002.11 Annual reports.

(a) Every manufacturer of products listed under § 1002.61(b) and (c) shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a).

(b) The first annual report shall be submitted by September 1, 1971, with subsequent reports due annually thereafter. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

§ 1002.12 Reports of model changes.

Prior to the introduction into commerce of a new or modified model of a product listed in § 1002.61 for which an initial report under § 1002.10 was required, each manufacturer shall submit a report with respect to such new or modified model containing any changes in the information submitted in the initial report.

Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

§ 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Bureau of Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be addressed to the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852, and the reports and their envelopes shall be distinctly marked "Report on § 1002.20" and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Bureau of Radiological Health, the names of the persons involved;

(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and

(7) Any other pertinent information with respect to the accidental radiation occurrence.

Subpart D—Manufacturers' Records

§ 1002.30 Records to be maintained by manufacturers.

(a) Manufacturers of products listed under paragraphs (b) and (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) Description of the quality control procedures with respect to electronic product radiation safety.

(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed in paragraph (c) of § 1002.61 shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to § 1002.41.

§ 1002.31 Preservation and inspection of records.

(a) Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 1002.41, shall preserve such records for a period of 5 years from the date of the record.

(b) Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

(c) Upon request of the Director, Bureau of Radiological Health, a manufacturer of products listed in paragraph (c) of § 1002.61 shall submit to the Director, copies of the records required to

be maintained by paragraph (b) of § 1002.30.

Subpart E—Dealer and Distributor Records

§ 1002.40 Records to be maintained by dealers and distributors.

(a) Dealers and distributors of electronic products listed in paragraph (c) of § 1002.61, for which there are applicable Federal standards under this subchapter and for which the retail price is not less than $50, shall obtain and preserve for a period of 5 years from the date of the sale, award, or lease of each such product such information as is necessary to permit tracing of specific products to specific purchasers.

(b) Such information shall include:

(1) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred.

(2) Identification and brand name of the product.

(3) Model number and serial or other identification number of the product.

(4) Date of sale, award, or lease.

§ 1002.41 Records furnished to manufacturers by dealers and distributors.

(a) Information obtained by dealers and distributors pursuant to § 1002.40 shall immediately be forwarded to the appropriate manufacturer unless:

(1) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Director, Bureau of Radiological Health, that such information is required for purposes of section 359 of the Act; and

(2) The dealer or distributor, upon making the election under subparagraph (1) of this paragraph, promptly notifies the manufacturer and the Director, Bureau of Radiological Health, of such election; such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

(b) Every dealer or distributor obtaining information pursuant to this part shall take such steps as are necessary to insure that such information is furnished to the manufacturer prior to the time the dealer or distributor discontinues the dealing in or distribution of electronic products.

§ 1002.42 Confidentiality of records furnished by dealers and distributors.

All information furnished to manufacturers by dealers and distributors pursuant to this part shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to section 359 of the Act.

Subpart F—Exemptions from Records and Reports Requirements

§ 1002.50 Special exemptions.

(a) Manufacturers of electronic products listed under paragraphs (b) and (c) of § 1002.61 may submit to the Director, Bureau of Radiological Health, with or subsequent to the submission of the initial report required by § 1002.10, a request, together with accompanying justification, that a product be exempted from the annual reporting and recordkeeping requirements. In addition to other information which may be required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested:

(1) Cannot emit electronic product radiation in sufficient intensity or of such quality under any conditions of use or product failure to be hazardous; or

(2) Is produced in such small numbers as to negate the need for continuous recordkeeping and reporting, and is to be used by trained individuals who are knowledgable of the hazards involved in such use.

(b) The Director, Bureau of Radiological Health, may exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which he may possess or may require of the manufacturer if he determines that such exemption is in keeping with the purposes of the Act.

§ 1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

Upon application therefore by the manufacturer, the Director, Bureau of Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

Subpart G—Codes for Reporting Listed Electronic Products

§ 1002.61 List of specific product groups.

(a) *Group A.* (1) Lasers and products containing lasers which have a reporting index number N, less than one (1). Reporting index numbers shall be calculated in accordance with Appendix A.

(2) Ultrasonic products.

(3) Microwave heating equipment not listed in paragraph (c) of this section.

(4) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes which are intended to be operated at voltages greater than 5,000 volts but less than 15,000 volts.

(b) *Group B.* (1) Television receivers which, on or after the effective date of this subpart, meets the Federal standard in effect on June 1, 1971, provided also that the voltage on the cathode ray tube and any other vacuum tube component cannot exceed 15,000 volts under the test conditions required by the Federal standard at that time.

(2) High voltage vacuum switches, high voltage rectifier tubes, shunt regulator tubes, and cathode ray tubes, which are intended to operate at voltages of 15,000 volts or greater.

(c) *Group C.* (1) Products subject to Federal standards prescribed under Parts 1010, 1020, and 1030 of this Subchapter J except for television receivers described in paragraph (b)(1) of this section.

(2) Products which are intended to produce x radiation.

(3) Microwave ovens intended to be used in homes, restaurants, food vending or service establishments, on interstate carriers and in similar locations.

(4) Microwave diathermy machines.

(5) Lasers and products or devices containing lasers which have a reporting index number of N, equal to or greater than one (1). Reporting index numbers shall be calculated in accordance with Appendix A.

Appendix A—Laser Reporting Index Number

(a) For laser products, the reporting index number N, shall be calculated using the relation $N = BU/A$. The appropriate value of B may be determined from Table 1 for a given wave-length. U is the radiant energy in joules (J). For continuous operation, U is the radiant energy per second in the laser emission. For single pulse operation, U is the true radiant energy per pulse. For repetitively pulsed lasers, reporting index numbers will be computed using both energy per pulse and energy per second. When computing the reporting index number using energy per pulse, that value of B corresponding to the pulse duration of the laser emission in Table 1 will be used. When computing the reporting index number using energy per second, that value of B found in the column "continuous to 0.1 sec" of Table 1 will be used.

(b) A, as used in the relation above, is the actual beam area in square centimeters. For parallel or divergent beams, A is measured at 30 centimeters (cm) from the permanent instrument housing[1] at the points of closest approach to the exit port or ports of the laser beam; for convergent beams, A is measured at that distance from the permanent instrument housing which results in a value of N which is maximal.

(c) If more than one value of N can be determined for a given product, the largest value shall be used for reporting purposes. When simultaneous emission of more than one wavelength occur, an individual reporting index number shall be calculated for each wavelength. The sum of the individual reporting index numbers shall be used as the

Table 1

Wavelength in micrometers	Values of B for different laser pulse durations		
	Continuous to 0.1 sec	0.1 to 10^{-6} sec	Less than 10^{-6} sec
μm	cm^2/J	cm^2/J	cm^2/J
0.40–0.79	23,000	160,000	2,000,000
0.80–0.99	3,700	26,000	320,000
1.00–1.19	1,100	8,000	100,000
1.20–1.39	100	670	8,000
1.40–1.60	2	17	200
Greater than 1.60	1	10	100

[1] "Permanent instrument housing" means that exterior part of the product, without which the laser beam cannot be produced.

reporting index number for the product. Where N cannot be calculated, a reporting index number of 1,000 shall be used.

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

Subpart A—General Provisions

Sec.

1003.1 Applicability.
1003.2 Defect in an electronic product.
1003.5 Effect of regulations on other laws.

Subpart B—Discovery of Defect or Failure to Comply

1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.
1003.11 Determination by Secretary that product fails to comply or has a defect.

Subpart C—Notification

1003.20 Notification by the manufacturer to the Secretary.
1003.21 Notification by the manufacturer to affected persons.
1003.22 Copies of communications sent to purchasers, dealers, or distributors.

Subpart D—Exemptions from Notification Requirements

1003.30 Application for exemption from notification requirements.
1003.31 Granting the exemption.

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g.

Subpart A—General Provisions

§ 1003.1 Applicability.

The provisions of this part are applicable to electronic products which were manufactured after October 18, 1968.

§ 1003.2 Defect in an electronic product.

For the purpose of this part, an electronic product shall be considered to have a defect which relates to the safety of use by reason of the emission of electronic product radiation if:

(a) It is a product which does not utilize the emission of electronic product radiation in order to accomplish its purpose, and from which such emissions are unintended, and as a result of its design, production or assembly (1) it emits electronic product radiation which creates a risk of injury, including genetic injury, to any person, or (2) it fails to conform to its design specifications relating to electronic radiation emissions; or

(b) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production or assembly it (1) fails to conform to its design specifications relating to the emission of electronic product radiation; or (2) without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person; or (3) fails to accomplish the intended purpose.

§ 1003.5 Effect of regulations on other laws.

The remedies provided for in this subchapter shall be in addition to and not in substitution for any other remedies provided by law and shall not relieve any person from liability at common law or under statutory law.

Subpart B—Discovery of Defect or Failure to Comply

§ 1003.10 Discovery of defect or failure of compliance by manufacturer; notice requirements.

Any manufacturer who discovers that any electronic product produced, assembled, or imported by him, which product has left its place of manufacture, has a defect or fails to comply with an applicable Federal standard shall:

(a) Immediately notify the Secretary in accordance with § 1003.20, and

(b) Except as authorized by § 1003.30, furnish notification with reasonable promptness to the following persons:

(1) The dealers or distributors to whom such product was delivered by the manufacturer; and

(2) The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

§ 1003.11 Determination by Secretary that product fails to comply or has a defect.

(a) If, the Secretary, through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable Federal standard issued pursuant to the Act or has a defect, he shall immediately notify the manufacturer of the product in writing specifying:

(1) The defect in the product or the manner in which the product fails to comply with the applicable Federal standard;

(2) The Secretary's findings, with references to the tests, inspections, studies, or reports upon which such findings are based;

(3) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

(b) Every manufacturer who receives a notice under § 1003.11(a) shall immediately advise the Secretary in writing of the total number of such product units produced and the approximate number of such product units which have left the place of manufacture.

(c) If, after the expiration of the period of time specified in the notice, the Secretary determines that the product has a defect or does not comply with an applicable Federal standard and the manufacturer has not applied for an exemption, he shall direct the manufacturer to furnish the notification to the persons specified in § 1003.10(b) in the manner specified in § 1003.21. The manufacturer shall within 14 days from the date of receipt of such directive furnish the required notification.

Subpart C—Notification

§ 1003.20 Notification by the manufacturer to the Secretary.

The notification to the Secretary required by § 1003.10(a) shall be confirmed in writing and, in addition to other relevant information which the Secretary may require, shall include the following:

(a) Identification of the product or products involved;

(b) The total number of such product units so produced, and the approximate number of such product units which have left the place of manufacture;

(c) The expected usage for the product if known to the manufacturer;

(d) A description of the defect in the product or the manner in which the product fails to comply with an applicable Federal standard;

(e) An evaluation of the hazards reasonably related to defect or the failure to comply with the Federal standard;

(f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the Federal standard;

(g) The date and circumstances under which the defect was discovered; and

(h) The identification of any trade secret information which the manufacturer desires kept confidential.

§ 1003.21 Notification by the manufacturer to affected persons.

(a) The notification to the persons specified in § 1003.10(b) shall be in writing and, in addition to other relevant information which the Secretary may require, shall include:

(1) The information prescribed by § 1003.20 (a), (d), and instructions with respect to the use of the product pending the correction of the defect;

(2) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply; and

(3) The following statement:

The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable Federal standard in accordance with a plan to be approved by the Secretary of Health, Education, and Welfare, the details of which will be included in a subsequent communication to you.

Provided, That if at the time the notification is sent, the Secretary has approved a plan for the repair, replacement or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

(b) The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this section.

(1) No. 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.

(2) The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle 3¾ inches wide and 2¼ inches high:

IMPORTANT
ELECTRONIC PRODUCT
RADIATION WARNING

The statement shall be in three lines, all capitals, and centered. "Important" shall be in 36-point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in 36-point Gothic Condensed type.

(3) Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for mailings other than those required by this part.

(c) The notification shall be sent:

(1) By certified mail to purchasers of the product and to subsequent transferees.

(2) By certified mail or other more expeditious means to dealers and distributors.

(d) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

§ 1003.22 Copies of communications sent to purchasers, dealers or distributors.

(a) Every manufacturer of electronic products shall furnish to the Secretary a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable Federal standard.

(b) In the event the Secretary deems the content of such notices to be insufficient to protect the public health and safety, the Secretary may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means he deems appropriate.

Subpart D—Exemptions From Notification Requirements

§ 1003.30 Application for exemption from notification requirements.

(a) A manufacturer may at the time of giving the written confirmation required by § 1003.20 or within 15 days of the receipt of any notice from the Secretary pursuant to § 1003.11(a), apply for an exemption from the requirement of notice to the persons specified in § 1003.10(b).

(b) The application for exemption shall contain the information required by § 1003.20 and in addition shall set forth in detail the grounds upon which the exemption is sought.

§ 1003.31 Granting the exemption.

(a) If, in the judgment of the Secretary, the application filed pursuant to § 1003.30 states reasonable grounds for an exemption from the requirement of notice, the Secretary shall give the manufacturer written notice specifying a reasonable period of time during which he may present his views and evidence in support of the application.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable.

(c) If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Secretary's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Secretary shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

(1) The electronic product or products for which the exemption has been issued; and

(2) Such conditions as the Secretary deems necessary to protect the public health and safety.

PART 1004—REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS

Sec.

1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.
1004.2 Plans for the repair of electronic products.
1004.3 Plans for the replacement of electronic products.
1004.4 Plans for refunding the cost of electronic products.
1004.6 Approval of plans.

AUTHORITY: Sec. 359, 82 Stat. 1180; 42 U.S.C. 263g.

§ 1004.1 Manufacturer's obligation to repair, replace, or refund cost of electronic products.

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in § 1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or (2) replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or (3) make a refund of the cost of the product to the purchaser.

(b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to § 1004.6 of this part.

§ 1004.2 Plans for the repair of electronic products.

Every plan for bringing an electronic product into conformity with applicable Federal standards or for remedying any defect in such product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect.

(d) The manner in which the operations described in paragraph (c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed.

(e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action.

(f) A time limit, reasonable in light of the circumstances, for completion of the operations.

(g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at his expense, will repair the electronic product involved, (2) of the method by which the manufacturer will obtain access to or possession of the product to make such repairs, (3) that the manufacturer will reimburse such persons for any transportation expenses incurred in connection with making such repairs, and (4) of the manner in which such reimbursement will be effected.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products repaired.

§ 1004.3 Plans for the replacement of electronic products.

Every plan for replacing an electronic product with a like or equivalent product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product to be replaced.

(b) A description of the replacement product in sufficient detail to support the manufacturer's contention that the replacement product is like or equivalent to the product being replaced.

(c) The approximate number of defective product units which have left the place of manufacture.

(d) The manner in which the replacement operation will be effected including the procedure for obtaining possession of the product to be replaced.

(e) A time limit, reasonable, in light of the circumstances for completion of the replacement.

(f) The steps which the manufacturer will take to insure that the defective product will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(g) The system by which the manufacturer will provide reimbursement for any expenses for transportation of such product incurred in connection with effecting the replacement.

(h) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at its expense, will replace the electronic product involved, (2) of the method by which the manufacturer will obtain possession of the product and effect the replacement, (3) that the manufacturer will reimburse such persons for any transportation expenses incurred in connection with effecting such replacement, and (4) of the manner in which such reimbursement will be made.

(i) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of electronic products replaced.

§ 1004.4 Plans for refunding the cost of electronic products.

Every plan for refunding the cost of an electronic product shall be submitted to the Secretary in writing, and in addition to other relevant information which the Secretary may require, shall include:

(a) Identification of the product involved.

(b) The approximate number of defective product units which have left the place of manufacture.

(c) The manner in which the refund operation will be effected including the procedure for obtaining possession of the product for which the refund is to be made.

(d) The steps which the manufacturer will take to insure that the defective products will not be reintroduced into commerce, until it complies with each applicable Federal standard and has no defect relating to the safety of its use.

(e) A time limit, reasonable in light of the circumstances, for obtaining the product and making the refund.

(f) A statement that the manufacturer will refund the cost of such product together with the information the manufacturer has used to determine the amount of the refund.

(g) The text of the statement which the manufacturer will send to the persons specified in § 1003.10(b) of this chapter informing such persons (1) that the manufacturer, at his expense, will refund the cost of the electronic product plus any transportation costs, (2) of the amount to be refunded exclusive of transportation costs, (3) of the method by which the manufacturer will obtain possession of the product and make the refund.

(h) An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of refunds made.

§ 1004.6 Approval of plans.

If, after review of any plan submitted pursuant to this subchapter, the Secretary determines that the action to be taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under § 1004.1 in a manner designed to encourage the public to respond to the proposal, the Secretary will send written notice of his approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Secretary deems necessary to protect the public health and safety.

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

Subpart A—General Provisions

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1005.1 Applicability.
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1005.3 Importation of noncomplying goods prohibited.

Subpart B—Inspection and Testing

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1005.20 Hearing.
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1005.23 Bonds.
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1005.25 Service of process on manufacturers.

AUTHORITY: Secs. 215, 356, 58 Stat. 690, 82 Stat. 1174; 42 U.S.C. 216, 263d.

Subpart A—General Provisions

§ 1005.1 Applicability.

(a) The provisions of §§ 1005.1 through 1005.24 are applicable to electronic products which are subject to the standards prescribed in Parts 1010, 1020, and 1030 of this chapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

§ 1005.2 Definitions.

As used in this part:

The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 358 of the Act (42 U.S.C. 268f) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 358(h) of the Act (42 U.S.C. 263f(h)). Merchandise refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§ 1005.21 and 1005.22.

Subpart B—Inspection and Testing

§ 1005.10 Notice of sampling.

When a sample of a product to be offered for importation has been requested by the Secretary, the District Director of Customs having jurisdiction over the shipment shall, upon the arrival of the shipment, procure the sample and shall give to its owner or consignee prompt notice of the delivery or of the intention to deliver such sample to the Secretary. If the notice so requires, the owner or consignee will hold the shipment of which the sample is typical and not release such shipment until he receives notice of the results of the tests of the sample from the Secretary, stating that the product is in compliance with the requirements of the Act. The District Director of Customs will be given the results of the tests. If the Secretary notifies the District Director of Customs that the product does not meet the requirements of the Act, the District Director of Customs shall require the exportation or destruction of the shipment in accordance with customs laws.

§ 1005.11 Payment for samples.

The Department of Health, Education, and Welfare will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of the Radiation Control for Health and Safety Act of 1968. Billing for reimbursement shall be made by the owner or consignee to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. Payment for samples will not be made if the sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

Subpart C—Bonding and Compliance Procedures

§ 1005.20 Hearing.

(a) If, from an examination of the sample or otherwise, it appears that the product may be subject to a refusal of admission, the Secretary shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony unless the owner or consignee indicates his intention to

bring the product into compliance. Upon timely request, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article and may be introduced orally or in writing.

(b) If the owner or consignee submits or indicates his intention to submit an application for permission to perform such action as is necessary to bring the product into compliance with the Act, such application shall include the information required by § 1005.21.

(c) If the application is not submitted at or prior to the hearing, the Secretary may allow a reasonable time for filing such application.

§ 1005.21 Application for permission to bring product into compliance.

Application for permission to perform such action as is necessary to bring the product into compliance with the Act may be filed only by the owner, consignee, or manufacturer and, in addition to any other information which the Secretary may reasonably require, shall:

(a) Contain a detailed proposal for bringing the product into compliance with the Act;

(b) Specify the time and place where such operations will be effected and the approximate time for their completion; and

(c) Identify the bond required to be filed pursuant to § 1005.23 of this part.

§ 1005.22 Granting permission to bring product into compliance.

(a) When permission contemplated by § 1005.21 is granted, the Secretary shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of a representative of the Department of Health, Education, and Welfare;

(4) A reasonable time limit for completing the operations; and

(5) Such other conditions as he finds necessary to maintain adequate supervision and control over the product.

(b) Upon receipt of a written request for an extension of time to complete the operations necessary to bring the product into compliance, the Secretary may grant such additional time as he deems necessary.

(c) The notice of permission may be amended upon a showing of reasonable grounds thereof and the filing of an amended application for permission with the Secretary.

(d) If ownership of a product included in a notice of permission changes before the operations specified in the notice have been completed, the original owner will remain responsible under its bond, unless the new owner has executed a superseding bond on customs Form 7601 and obtained a new notice.

(e) The Secretary will notify the District Director of Customs having jurisdiction over the shipment involved, of the determination as to whether or not the product has in fact been brought into compliance with the Act.

§ 1005.23 Bonds.

The bond required under section 360 (b) of the Act shall be executed by the owner or consignee on the appropriate form of a customs single-entry bond, customs Form 7551 or term bond, customs Form 7553 or 7595, containing a condition for the redelivery of the shipment or any part thereof not complying with the laws and regulations governing its admission into the commerce of the United States upon demand of the District Director of Customs and containing a provision for the performance of any action necessary to bring the product into compliance with all applicable laws and regulations. The bond shall be filed with the District Director of Customs.

§ 1005.24 Costs of bringing product into compliance.

The costs of supervising the operations necessary to bring a product into compliance with the Act shall be paid by the owner or consignee who files an application pursuant to § 1005.21 and executes a bond under section 360(b) of the Act. Such costs shall include:

(a) Travel expenses of the supervising officer;

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law;

(c) Services of the supervising officer to be calculated at a flat rate of $12 per hour (which shall include administrative expense) except that such services performed by a customs officer and subject to the provisions of the Act of February 13, 1911, as amended (section 5, 36 Stat. 901, as amended; 19 U.S.C. 267), shall be calculated as provided by that Act;

(d) The minimum charge for services of supervising officers shall be not less than the charge for 1 hour and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than one-half hour.

§ 1005.25 Service of process on manufacturers.

(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) The designation shall be addressed to the Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. It shall be in writing and dated; all signatures shall be in ink. The designation shall be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the persons or person signing the designation shall certify that it is so made. The designation shall disclose the manufacturer's full legal name and the name(s) under which he conducts his business, if applicable, his principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation shall identify the marks, trade names, or other designations of origin which these products bear. The designation shall provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent shall be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

(c) Service of any process, notice, order, requirement, or decision specified in section 360(d) of the Radiation Control for Health and Safety Act of 1968 may be made by registered or certified mail addressed to the agent with return receipt requested, or in any other manner authorized by law. In the absence of such a designation or if for any reason service on the designated agent cannot be effected, service may be made as provided in section 360(d) by posting such process, notice, order, requirement, or decision in the Office of the Director, Bureau of Radiological Health and publishing a notice that such service was made in the FEDERAL REGISTER.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

Subpart A—General Provisions

Sec.
1010.1 Scope.
1010.2 Certification.
1010.3 Identification.

Subpart B—Alternate Test Procedures

1010.13 Special test procedures.

Subpart C—Exportation of Electronic Products

1010.20 Electronic products intended for export.

AUTHORITY: Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f.

Subpart A—General Provisions

§ 1010.1 Scope.

The standards listed in this part, and Parts 1020 and 1030 of this chapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined

necessary for the protection of the public health and safety.

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under Parts 1020 and 1030 of this chapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under Parts 1020 and 1030 of this chapter.

(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Secretary may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standard prescribed under Parts 1020 and 1030 of this chapter.

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Secretary may approve an alternate means by which such certification may be provided.

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under Parts 1020 and 1030 of this chapter is applicable shall set forth the information specified in subparagraphs (1) and (2) of this paragraph. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard.

(1) The full name and address of the manufacturer of the product: Abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Secretary with sufficient information to identify the manufacturer of the product.

(2) The month, year, and place of manufacture: This information may be expressed in code provided the manufacturer has previously supplied the Secretary with the key to such code.

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Secretary may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which is applicable a standard under Parts 1020 and 1030 of this chapter shall provide the Secretary with a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

Subpart B—Alternate Test Procedures

§ 1010.13 Special test procedures.

The Secretary may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standard for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

Subpart C—Exportation of Electronic Products

§ 1010.20 Electronic products intended for export.

The performance standard prescribed in Parts 1020 and 1030 of this chapter shall not apply to any electronic product which is intended solely for export if (a) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (b) such product meets all the applicable requirements of the country to which such product is intended for export.

PART 1020—PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS

Sec.

1020.10 Television receivers.
1020.20 Cold-cathode gas discharge tubes.
1020.30 Diagnostic x-ray systems and their major components.
1020.31 Radiographic equipment.
1020.32 Fluoroscopic equipment.

AUTHORITY: Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f.

§ 1020.10 Television receivers.

(a) *Applicability.* The provisions of this section are applicable to television receivers manufactured subsequent to January 15, 1970.

(b) *Definitions.* (1) "External surface" means the cabinet or enclosure provided by the manufacturer as part of the receiver. If a cabinet or enclosure is not provided as part of the receiver, the external surface shall be considered to be a hypothetical cabinet, the plane surfaces of which are located at those minimum distances from the chassis sufficient to enclose all components of the receiver except that portion of the neck and socket of the cathode-ray tube which normally extends beyond the plane surfaces of the enclosure.

(2) "Maximum test voltage" means 130 root mean square volts if the receiver is designed to operate from nominal 110 to 120 root mean square volt power sources. If the receiver is designed to operate from a power source having some voltage other than from nominal 110 to 120 root mean square volts, maximum test voltage means 110 percent of the nominal root mean square voltage specified by the manufacturer for the power source.

(3) "Service controls" means all of those controls on a television receiver provided by the manufacturer for purposes of adjustment which, under normal usage, are not accessible to the user.

(4) "Television receiver" means an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television.

(5) "Usable picture" means a picture in synchronization and transmitting viewable intelligence.

(6) "User controls" means all of those controls on a television receiver, provided by the manufacturer for purposes of adjustment, which on a fully assembled receiver under normal usage, are accessible to the user.

(c) *Requirements*—(1) *Exposure rate limit.* Radiation exposure rates produced by a television receiver shall not exceed 0.5 milliroentgens per hour at a distance of five (5) centimeters from any point on the external surface of the receiver, as measured in accordance with this section.

(2) *Measurements.* Compliance with the exposure rate limit defined in subparagraph (1) of this paragraph shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten (10) square centimeters and no dimension larger than five (5) centimeters. Measurements made with instruments having other areas must be corrected for spatial nonuniformity of the radiation field to obtain the exposure rate average over a ten (10) square centimeter area.

(3) *Test conditions.* All measurements shall be made with the receiver displaying a usable picture and with the power source operated at supply voltages up to the maximum test voltage of the receiver and, as applicable, under the following specific conditions:

(i) On television receivers manufactured subsequent to January 15, 1970, measurements shall be made with all user controls adjusted so as to produce maximum x-radiation emissions from the receiver.

(ii) On television receivers manufactured subsequent to June 1, 1970, measurements shall be made with all user controls and all service controls adjusted to combinations which result in the production of maximum x-radiation emissions.

(iii) On television receivers manufactured subsequent to June 1, 1971, measurements shall be made under the conditions described in subdivision (ii) of this subparagraph, together with condi-

tions identical to those which result from that component or circuit failure which maximizes x-radiation emissions.

(4) *Critical component warning.* The manufacturer shall permanently affix or inscribe a warning label, clearly legible under conditions of service, on all television receivers which could produce radiation exposure rates in excess of the requirements of this section as a result of failure or improper adjustment or improper replacement of a circuit or shield component. The warning label shall include the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

§ 1020.20 Cold-cathode gas discharge tubes.

(a) *Applicability.* The provisions of this section are applicable to cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x radiation as specified herein.

(b) *Definitions.* "Beam blocking device" means a movable or removable portion of any enclosure around a cold-cathode gas discharge tube, which may be opened or closed to permit or prevent the emergence of an exit beam.

"Cold-cathode gas discharge tube" means an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

"Exit beam" means that portion of the radiation which passes through the aperture resulting from the opening of the beam blocking device.

"Exposure" means the sum of the electrical charges on all of the ions of one sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air divided by the mass of the air in the volume element. The special unit of exposure is the roentgen. One (1) roentgen equals 2.58×10^{-4} coulombs/kilogram.

(c) *Requirements.* (1) Exposure rate limit:

(i) Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed 10 mR./hr. at a distance of thirty (30) centimeters from any point on the external surface of the tube, as measured in accordance with this section.

(ii) The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x radiation, with the beam blocking device in the open position, shall not exceed π (Pi) steradians.

(2) Measurements:

(i) Compliance with the exposure rate limit defined in (c)(1)(i) shall be determined by measurements averaged over an area of one hundred (100) square centimeters with no linear dimension greater than twenty (20) centimeters.

(ii) Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty (30) centimeters from any point on the external surface of the enclosure, provided:

(*a*) In the case of enclosures containing tubes designed primarily to demonstrate the production of x radiation, measurements shall be made with any beam blocking device in the beam blocking position, or

(*b*) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.

(3) Test conditions:

(i) Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.

(ii) Measurements shall be made with the tube operated under forward and reverse polarity.

(4) Instructions, labels, and warnings:

(i) Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.

(ii) Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and: (a) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x rays in excess of allowable limits; and (b) in the case of tubes designed primarily to demonstrate the production of x radiation, a warning that this device produces x rays when energized.

(iii) The tag or label required by this paragraph shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

§ 1020.30 Diagnostic x-ray systems and their major components.

(a) *Applicability.* The provisions of this section and §§ 1020.31 and 1020.32 are applicable as specified herein to:

(1) The following components of diagnostic x-ray systems which are manufactured after August 1, 1974. Tube housing assemblies, x-ray controls, x-ray high-voltage generators, fluoroscopic imaging assemblies, tables, cradles, film changers, casette holders, and beam-limiting devices; and

(2) Diagnostic x-ray systems incorporating one or more of such components; however, such x-ray systems shall be required to comply only with those provisions of this section and §§ 1020.31 and 1020.32 which relate to the components certified in accordance with paragraph (c) of this section and installed into the systems.

(b) *Definitions.* As used in this section and §§ 1020.31 and 1020.32, the following definitions apply:

(1) "Accessible surface" means the external surface of the enclosure or housing provided by the manufacturer.

(2) "Aluminum equivalent" means the thickness of aluminum (type 1100 alloy)[1] affording the same attenuation, under specified conditions, as the material in question.

(3) "Assembler" means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem.

(4) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or aluminum alloy having equivalent attenuation.

(5) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(6) "Beam axis" means a line from the source through the centers of the x-ray fields.

(7) "Beam-limiting device" means a device which provides a means to restrict the dimensions of the x-ray field.

(8) "Coefficient of variation" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C=\frac{s}{\overline{X}}=\frac{1}{\overline{X}}\left[\sum_{i=1}^{n}\frac{(X_i-\overline{X})^2}{n-1}\right]^{\frac{1}{2}}$$

where

s = Estimated standard deviation of the population.

$\overline{X}$ = Mean value of observations in sample.

X_i = ith observation sampled.

n = Number of observations sampled.

(9) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

(10) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(11) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(12) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

(13) "Equipment" means x-ray equipment.

(14) "Exposure" means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.

(15) "Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the

[1] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper, as given in "Aluminum Standards and Data" (1969). Copies may be obtained from: The Aluminum Association, New York, NY.

cathode is due solely to the action of an electric field.

(16) "Fluoroscopic imaging assembly" means a component which comprises a reception system in which x-ray photons produce a fluoroscopic image. It includes equipment housings, electrical interlocks if any, the primary protective barrier, and structural material providing linkage between the image receptor and the diagnostic source assembly.

(17) "General purpose radiographic x-ray system" means any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

(18) "Half-value layer, HVL" means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

(19) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

(20) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(i) The useful beam and

(ii) Radiation produced when the exposure switch or timer is not activated.

(21) "Leakage technique factors" means the technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

(i) For capacitor energy storage equipment, the maximum rated number of exposures in an hour for operation at the maximum rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs (mAs) or the minimum obtainable from the unit, whichever is larger.

(ii) For field emission equipment rated for pulsed operation, the maximum rated number of x-ray pulses in an hour for operation at the maximum rated peak tube potential.

(iii) For all other equipment, the maximum rated continuous tube current for the maximum rated peak tube potential.

(22) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(23) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100(V_n - V_l)/V_l$$

where

V_n = No-load line potential and
V_l = Load line potential.

(24) "Maximum line current" means the rms current in the supply line of an x-ray machine operating at its maximum rating.

(25) "Peak tube potential" means the maximum value of the potential difference across the x-ray tube during an exposure.

(26) "Primary protective barrier" means the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes.

(27) "Rated line voltage" means the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate.

(28) "Rated output current" means the maximum allowable load current of the x-ray high-voltage generator.

(29) "Rated output voltage" means the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator.

(30) "Rating" means the operating limits specified by the manufacturer.

(31) "Recording" means producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

(32) "Response time" means the time required for an instrument system to reach 90 percent of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state midscale reading.

(33) "Source" means the focal spot of the x-ray tube.

(34) "Source-image receptor distance, (SID)" means the distance from the source to the center of the input surface of the image receptor.

(35) "Stationary equipment" means equipment which is installed in a fixed location.

(36) "Technique factors" means the conditions of operation. They are specified as follows:

(i) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

(ii) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

(iii) For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

(37) "Tube" means an x-ray tube, unless otherwise specified.

(38) "Tube housing assembly" means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when they are contained within the tube housing.

(39) "Tube rating chart" means the set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

(40) "Useful beam" means the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

(41) "Variable-aperture beam-limiting device" means a beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

(42) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons produce a visible image.

(43) "X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment which controls the technique factors of an x-ray exposure.

(44) "X-ray equipment" means an x-ray system, subsystem, or component thereof.

(45) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(46) "X-ray high-voltage generator" means a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

(47) "X-ray system" means an assemblage of components for the controlled production of x rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

(48) "X-ray subsystem" means any combination of two or more components of an x-ray system for which there are requirements specified in this section and §§ 1020.31 and 1020.32.

(49) "X-ray tube" means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) *Certification of components.* Each component subject to this section and §§ 1020.31 and 1020.32 shall be certified by the manufacturer thereof as a product which meets all applicable standards in accordance with the provisions of § 1010.2 of this chapter. Certification that the product conforms to all applicable standards under this part shall be construed to mean that the component can meet the applicable provisions of this section and §§ 1020.31 and 1020.32 if installed in a diagnostic x-ray system in accordance with instructions.

(d) *Certification by assembler.* An assembler who installs one or more components certified as required by paragraph (c) of this section into an x-ray system shall install certified components that are of the type required by § 1020.31 or § 1020.32 and, except as provided for in subparagraph (2) of this paragraph, shall assemble, install, adjust, and test the certified components in accordance with the instructions of their respective

manufacturers. All assemblers who install certified components shall file a report of such assembly as specified in subparagraphs (1) and (2) of this paragraph. The report shall be construed as the assembler's certification and identification under §§ 1010.2 and 1010.3 of this chapter. All assembler reports shall be on a form prescribed by and available from the Director, Bureau of Radiological Health, 5600 Fishers Lane, Rockville, MD 20852. Completed reports shall be submitted to the Director, the purchaser, and, where applicable, to the State agency responsible for radiation protection, within 15 days following completion of the assembly.

(1) *Reporting compliance.* An assembler who installs one or more certified components into an x-ray system or subsystem, having properly followed the assembly instructions provided him by the component manufacturer, shall certify to this by filing a report containing the information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type and intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified components which were assembled or installed by him into the x-ray system or subsystem in accordance with the instructions of the component manufacturers, identifying the components by type, manufacturer, model number. and serial number.

(vi) An affirmation that the certified components listed pursuant to subdivision (v) of this subparagraph were assembled according to the instructions provided by the manufacturer(s) of such components.

(vii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31 or § 1020.32.

(viii) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(2) *Reporting noncompatibility.* An assembler who installs a certified component into an x-ray system shall file a report indicating noncompatibility if he is unable to follow the instructions of the manufacturer of such certified component, provided other component(s) of the system do not meet the manufacturer's specifications for compatibility as given by the certified component manufacturer pursuant to paragraph (g) of this section and provided there is no commercially available certified component of a similar type which is compatible with the x-ray system. In addition, the component(s) of the system not meeting the specification for compatibility must either be of a type listed in paragraph (a)(1) of this section which does not bear a certification label due to date of manufacture, or if it is a component not of the type listed in paragraph (a)(1) of this section, it must have been purchased as new prior to August 1, 1974. No assembler shall perform any modification of a certified component which will adversely affect the performance of the certified component with respect to the requirements of this section and §§ 1020.31 and 1020.32. The assembler shall file a report indicating noncompatibility containing information prescribed on the form which shall include the following:

(i) The full name and address of the assembler and the date of assembly or installation.

(ii) The name and address of the purchaser and the location and specific identification of the x-ray system or subsystem.

(iii) An affirmation that all instruction manuals and other information as required by paragraph (h) of this section applicable to the newly installed x-ray equipment have been delivered to the purchaser.

(iv) A statement of the type or intended use of the x-ray system or subsystem into which the certified components were assembled or installed, such as "radiographic—stationary general purpose."

(v) A list of all certified component(s) which were assembled or installed by him into the x-ray system or subsystem and which could not be assembled, installed, adjusted, and tested in accordance with the manufacturer's instructions due to reasons specified in this subparagraph (this paragraph (d)(2)), identifying the components by type, manufacturer, model number, and serial number.

(vi) An affirmation that the certified component(s) listed pursuant to subdivision (v) of this subparagraph could not be assembled, installed, adjusted, and tested in accordance with the installation instructions of their respective manufacturers due to reasons specified in this subparagraph (this paragraph (d)(2)), and that no certified component was modified so as to adversely affect its performance with respect to the requirements of this section and §§ 1020.31 and 1020.32.

(vii) For each certified component listed pursuant to subdivision (v) of this subparagraph, a full and complete explanation of why the manufacturer's installation instructions could not be followed in performing the assembly, including a listing by type, manufacturer, and model number of the incompatible component(s) already in the system, and either evidence of its date of purchase as new if it is not a type of component listed in paragraph (a)(1) of this section, or if it is a type of component listed in paragraph (a)(1) of this section, a statement that it did not bear a certification label due to its date of manufacture.

(viii) An affirmation that all certified components installed in the x-ray system or subsystem were of the type required by § 1020.31 or § 1020.32.

(ix) An affirmation that a copy of this report will be transmitted to the purchaser and, where applicable, to the State agency responsible for radiation protection, in accordance with the requirements of this paragraph.

(e) *Identification of x-ray components.* In addition to the identification requirements specified in § 1010.3 of this chapter, manufacturers of components subject to this section and §§ 1020.31 and 1020.32, except high-voltage generators contained within tube housings, and beam-limiting devices which are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product, so as to be legible and accessible to view.

(1) *Tube housing assemblies.* In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.

(2) *Replacement of tubes.* The replacement of an x-ray tube in a previously manufactured tube housing assembly shall constitute manufacture of a new tube housing assembly and the manufacturer shall be subject to the provisions of subparagraph (1) of this paragraph. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels which are no longer applicable.

(f) *Limits of responsibility*—(1) *Manufacturer.* The manufacturer of a certified component installed or assembled into an x-ray system or subsystem by another person shall not be liable for the noncompliance of such component which is attributable solely to the improper installation or assembly of the component into the system, but shall be held responsible for noncompliance if improper assembly was a result of inadequate instructions provided by such component manufacturer.

(2) *Assembler.* The person who certified as to the assembly of an x-ray system or subsystem shall not be liable for noncompliance of a certified component if such assembly is in accordance with the instructions provided by the manufacturer of the component, but shall be held responsible for noncompliance of a component which is attributable solely to improper assembly or installation into the system or subsystem.

(g) *Information to be provided to assemblers.* Manufacturers of components listed in paragraph (a)(1) of this section shall provide to assemblers subject to paragraph (d) of this section and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing

of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 1020.31 and 1020.32 when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components and/or may list by manufacturer model number the components which are compatible.

(h) *Information to be provided for users.* Manufacturers of x-ray equipment shall provide for purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

(1) *All x-ray equipment.* For x-ray equipment to which this section and §§ 1020.31 and 1020.32 are applicable, there shall be provided:

(i) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment and

(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 1020.31 and 1020.32.

(2) *Tube housing assemblies.* For each tube housing assembly, there shall be provided:

(i) Statements of the maximum rated peak tube potential, leakage technique factors, the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;

(ii) Cooling curves for the anode and tube housing; and

(iii) Tube rating charts.

If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self-rectified, single-phase half-wave rectified, single-phase full-wave rectified, three-phase six pulse, three-phase 12 pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation which affect its rating, specific identification of the difference in ratings shall be noted.

(3) *X-ray controls and generators.* For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

(i) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;

(ii) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, he shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(s);

(iii) A statement of the technique factors that constitute the maximum line current condition described in subdivision (ii) of this subparagraph;

(iv) In the case of battery-powered generators, a specification of the minimum state of charge necessary for proper operation;

(v) Generator rating and duty cycle;

(vi) A statement of the maximum deviation from the indication given by labeled control settings and/or meters during any exposure when the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated; and

(vii) A statement defining the measurement basis (or bases) upon which the exposure time, peak tube potential, tube current, and/or other technique factors are stated pursuant to subdivisions (iii) and (vi) of this subparagraph.

(4) *Variable-aperture beam-limiting device.* For each variable-aperture beam-limiting device, there shall be provided:

(i) Specifications of tube housing assemblies for which the device is designed or is compatible with respect to the requirements of paragraph (k) of this section and §§ 1020.31(d) and (e); and

(ii) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

(i) *Variances*—(1) *Criteria for variances.* Upon application by a manufacturer (including assembler), the Director, Bureau of Radiological Health, may grant a variance from one or more provisions of this section and §§ 1020.31 and 1020.32 applicable to any diagnostic x-ray system, subsystem, or component when he determines that the granting of such variance is in keeping with the purposes of the Act and that the requested variance:

(i) Is designed to have identifiable technical advantages and is to be used either as a prototype or experimental equipment for clinical evaluation, or

(ii) Is required for obtaining diagnostic information not obtainable with equipment meeting all the requirements of this section and §§ 1020.31 and 1020.32, or

(iii) Utilizes alternate means for providing protection at least equal to that provided by equipment which conforms to this section and §§ 1020.31 and 1020.32.

(2) *Applications for variances.* Applications for variances shall be submitted to the Director, Bureau of Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852, and shall include the following information:

(i) A description of the product and its intended use,

(ii) An explanation of how compliance with this section and §§ 1020.31 and 1020.32 would restrict this intended use,

(iii) A description of the manner in which it is proposed to deviate from the requirements of this section and §§ 1020.31 and 1020.32,

(iv) A description of the advantages to be derived from such deviation,

(v) An explanation of how alternate means of protection will be provided,

(vi) The number of units the applicant wishes to manufacture and/or for what period of time it is desired that the variance be in effect, and

(vii) In the case of prototype or experimental equipment, the proposed location of each unit.

(3) *Administration of variances.* (i) Written notification will be provided by the Director, Bureau of Radiological Health, to the manufacturer of the granting or refusal of a variance. Notification of an approved variance will state the number of units for which the variance is approved and/or the termination date of the variance. Variances will be identified by a number and date of issuance.

(ii) A public file of approved variances and information related to pending actions will be maintained by the Director, Bureau of Radiological Health, and, where applicable, affected State radiation regulatory authorities will be notified of action with respect to variances. Information containing trade secrets will be administered in accordance with the provisions of section 360A(e) of the Act.

(iii) After reasonable notice to the manufacturer and opportunity for a hearing, the variance will be withdrawn if the Director, Bureau of Radiological Health, deems that such withdrawal is necessary to protect the public health.

(iv) In the event that the Director, Bureau of Radiological Health, determines that an imminent public health hazard is presented by the continuation of a variance, he shall immediately withdraw such variance after due notification to the manufacturer. Such withdrawal shall not prejudice a manufacturer's opportunity for a hearing following the withdrawal.

(4) *Certification of equipment covered by variance.* The manufacturer of any diagnostic x-ray equipment for which a variance is granted shall modify the tag, label, or other certification required by §§ 1010.2 and 1010.3 of this chapter, or this section and §§ 1020.31 and 1020.32 to state:

(i) That the item is in conformity with this section and §§ 1020.31 and 1020.32 except with respect to those characteristics covered by the variance;

(ii) That the item is in conformity with the provisions of the variance; and

(iii) The assigned number of the variance and date assigned.

(j) *Warning label.* The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(k) *Leakage radiation from the diagnostic source assembly.* The leakage radiation from the diagnostic source assembly measured at a distance of 1 meter in any direction from the source shall not exceed 100 milliroentgens in 1 hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(l) *Radiation from components other than the diagnostic source assembly.* The radiation emitted by a component other than the diagnostic source assembly shall not exceed 2 milliroentgens in 1 hour at 5 centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(m) *Beam quality*—(1) *Half-value layer.* The half-value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I.

TABLE I

Design operating range (Kilovolts peak)	Measured potential (Kilovolts peak)	Half-value layer (Millimeters of aluminum)
Below 50	40	0.3
	45	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made. Positive means[2] shall be provided to insure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure.

(2) *Measuring compliance.* For capacitor energy storage equipment, compliance shall be determined with the maximum quantity of charge per exposure.

(n) *Aluminum equivalent of material between patient and image receptor.* The aluminum equivalent of each of the items listed in Table II, which are used between the patient and image receptor, shall not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam which has a half-value layer of 2.7 millimeters of aluminum. This requirement is applicable to front panel(s) of cassette holders and film changers provided by the manufacturer for purposes of patient support and/or to prevent foreign object intrusions. It does not apply to such items as a screen and its associated mechanical support panel or grids.

TABLE II

Item	Aluminum equivalent (millimeters)
Front panel(s) of cassette holder (total of all)	1.0
Front panel(s) of film changer (total of all)	1.0
Stationary tabletop	1.0
Moveable tabletop (including stationary subtop)	1.5
Cradle	2.0

(o) *Battery charge indicator.* On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

§ 1020.31 Radiographic equipment.

The provisions of this section apply to equipment for the recording of images, except those involving use of an image intensifier.

(a) *Control and indication of technique factors*—(1) *visual indication.* The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

(2) *Timers.* Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

(i) Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

(ii) During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) *Automatic exposure controls.* When an automatic exposure control is provided:

(i) Indication shall be made on the control panel when this mode of operation is selected;

(ii) When the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two pulses and the minimum exposure time for all other equipment shall be equal to or less than 1/60 second or a time interval required to deliver 5 mAs, whichever is greater;

(iii) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except when the x-ray tube potential is less than 50 kVp in which case the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

(iv) A visible signal shall indicate when an exposure has been terminated at the limits described in subdivision (iii) of this subparagraph, and manual resetting shall be required before further automatically timed exposures can be made.

(4) *Accuracy.* Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 1020.30(h)(3).

(b) *Reproducibility.* The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 1020.30(h)(3):

(1) *Coefficient of variation.* For any specific combination of selected technique factors, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05.

(2) *Measuring compliance.* Determination of compliance shall be based on 10 consecutive measurements taken within a time period of 1 hour. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within ±1 of the mean value for all measurements. In the case of automatic exposure controls, compliance shall be determined with the attenuation block placed in the primary beam, and the technique factors shall be such as to provide individual exposures of a minimum of 12 pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

(c) *Linearity.* The following requirement applies when the equipment allows a choice of x-ray tube current settings and is operated on a power supply as

[2] In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlock with the kilovoltage selector which will prevent x-ray emission if the minimum required filtration is not in place.

specified by the manufacturer in accordance with the requirements of § 1020.30 (h) (3) for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated.

(1) *Average exposure ratios.* The average ratios of exposure to the indicated milliampere-seconds product (mR/mAs) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum. This is:

$|\bar{X}_1 - \bar{X}_2| \leq 0.10\ (\bar{X}_1 + \bar{X}_2)$; where $\bar{X}_1$ and $\bar{X}_2$ are the average mR/mAs values obtained at each of two consecutive tube current settings.

(2) *Measuring compliance.* Determination of compliance will be based on 10 exposures at each of two consecutive x-ray tube current settings made within 1 hour. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors. Where tube current selection is continuous, $\bar{X}_1$ and $\bar{X}_2$ shall be obtained at current settings differing by no greater than a factor of 2.

(d) *Field limitation and alignment for mobile and stationary general purpose x-ray systems.* Except when spot-film devices are used, mobile and stationary general purpose radiographic x-ray systems shall meet the following requirements:

(1) *Variable x-ray field limitation.* There shall be provided a means for stepless adjustment of the size of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than 5 by 5 centimeters.

(2) *Visual definition.* (i) Means shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed 2 percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

(ii) When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than 4 in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than 3 in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination 3 millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination 3 millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of 1 millimeter.

(e) *Field limitation and alignment on stationary general purpose x-ray equipment.* Except when spot-film devices are used, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph (d) of this section:

(1) *Field indication and alignment.* (i) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within 2 percent of the SID, and to indicate the SID to within 2 percent;

(ii) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

(iii) Indication of field size dimensions and SID's shall be specified in inches and/or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those of the image receptor to within 2 percent of the SID when the beam axis is perpendicular to the plane of the image receptor; and

(iv) Compliance measurements will be made at discrete SID's and image receptor dimensions in common clinical use (such as SID's of 36, 40, 48, and 72 inches and nominal image receptor dimensions of 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

(2) *Positive beam limitation.* (i) Means shall be provided for positive beam limitation which will, at the SID for which the device is designed, either cause automatic adjustment of the x-ray field in the plane of the image receptor to the image receptor size within 5 seconds after insertion of the image receptor or, if adjustment is accomplished automatically in a time interval greater than 5 seconds or is manual, will prevent production of x rays until such adjustment is completed. At SID's at which the device is not intended to operate, the device shall prevent the production of x rays.

(ii) The x-ray field size in the plane of the image receptor, whether automatically or manually adjusted, shall be such that neither the length nor the width of the x-ray field differs from that of the image receptor by greater than 3 percent of the SID and that the sum of the length and width differences without regard to sign be no greater than 4 percent of the SID when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor.

(iii) The radiographic system shall be capable of operation, at the discretion of the operator, such that the field size at the image receptor can be adjusted to a size smaller than the image receptor. The minimum field size at a distance of 100 centimeters shall be equal to or less than 5 by 5 centimeters. Return to positive beam limitation as defined in subdivisions (i) and (ii) of this subparagraph shall occur upon a change in image receptor.

(iv) Positive beam limitation may be bypassed when radiography is conducted which does not use the cassette tray or permanently mounted vertical cassette holder, or when either the beam axis or table angulation is not within 10° of the horizontal or vertical during any part of the exposure, or during stereoscopic radiography. If the bypass mode is provided, return to positive beam limitation shall be automatic.

(v) A capability may be provided for overriding positive beam limitation in the event of system failure or to perform special procedures which cannot be performed in the positive mode. If so provided, a key shall be required to override the positive mode. It shall be impossible to remove the key while the positive mode is overriden.

(f) *Field limitation on radiographic x-ray equipment other than general purpose radiographic systems*—(1) *Equipment for use with intraoral image receptors.* Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters; and

(ii) If the minimum SSD is less than 18 centimeters, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) *X-ray systems designed for one image receptor size.* Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID.

(3) *Other x-ray systems.* Radiographic systems not specifically covered in paragraphs (d), (e), of this section, subparagraph (2) of this paragraph and paragraph (g) of this section, and systems covered in subparagraph (1) of this paragraph which are designed for use with extraoral as well as intraoral image receptors shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image recep-

tor to within 2 percent of the SID. These requirements may be met with:

(i) A system which performs in accordance with paragraphs (d) and (e) (1) of this section; or, when alignment means are also provided, may be met with either:

(ii) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed (each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed); or

(iii) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(g) *Field limitation and alignment for spot-film devices.* When a spot-film device is used, the following requirements shall apply:

(1) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot-film selector. Such adjustment shall be automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film.

(2) The total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor, when adjusted for full coverage of the selected portion of the image receptor, shall not exceed 3 percent of the SID. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID.

(3) It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(4) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within 2 percent of the SID.

(h) *Source-skin distance.* (1) X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

(i) Eighteen centimeters if operable above 50 kilovolts peak, or

(ii) Ten centimeters if not operable above 50 kilovolts peak.

(2) Mobile or portable x-ray systems other than dental shall be provided with means to limit source-to-skin distance to not less than 30 centimeters.

(i) *Beam-on indicators.* The x-ray control shall provide visual indication whenever x rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(j) *Multiple tubes.* Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

(k) *Standby radiation from capacitor energy storage equipment.* Radiation emitted from the x-ray tube when the exposure switch or timer is not activated shall not exceed a rate of 2 milliroentgens per hour at 5 centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The response time of the (radiation measuring) instrument system shall be no less than 3 and no greater than 20 seconds.

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The entire cross section of the useful beam shall be intercepted by the primary protective barrier of the fluoroscopic image assembly at any SID. The fluoroscopic tube shall not produce x rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier, if provided, shall not exceed 2 milliroentgens per hour at 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size at the greatest SID shall be equal to or less than 5 by 5 centimeters.

(2) *Image-intensified fluoroscopy.* For image-intensified fluoroscopic equipment the total misalignment of the edges of the x-ray field with the respective edges of the visible area of the image receptor along any dimension of the visually defined field in the plane of the image receptor shall not exceed 3 percent of the SID. The sum, without regard to sign, of the misalignment along any two orthogonal dimensions intersecting at the center of the visible area of the image receptor shall not exceed 4 percent of the SID. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. Means shall be provided to permit further limitation of the field. The minimum field size, at the greatest SID, shall be equal to or less than 5 by 5 centimeters.

(c) *Activation of tube.* X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Entrance exposure rate limits*—(1) *Equipment with automatic exposure rate control.* Fluoroscopic equipment which is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 10 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be required to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(2) *Equipment without automatic exposure rate control.* Fluoroscopic equip-

ment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of 5 roentgens per minute at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high level control is activated.

Special means of activation of high level controls, such as additional pressure applied continuously by the operator, shall be provided to avoid accidental use. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

(3) *Measuring compliance.* Compliance with this paragraph (d) shall be determined as follows:

(i) If the source is below the table, exposure rate shall be measured 1 centimeter above the tabletop or cradle.

(ii) If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(e) *Indication of potential and current.* During fluoroscopy and cinefluorography x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 1020.30(h)(3).

(f) *Source-skin distance.* Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile fluoroscopes. In addition, for image-intensified fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 1020.30(h).

(g) *Fluoroscopic timer.* Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x rays are produced until the timing device is reset.

(h) *Mobile fluoroscopes.* In addition to the foregoing requirements of this section, mobile fluoroscopes shall provide intensified imaging.

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

§ 1030.10 Microwave ovens.

(a) *Applicability.* The provisions of this standard are applicable to microwave ovens manufactured after October 6, 1971.

(b) *Definitions.* (1) "Microwave oven" means a device designed to heat, cook, or dry food through the application of electromagnetic energy at frequencies assigned by the Federal Communications Commission in the normal ISM heating bands ranging from 890 megahertz to 6,000 megahertz. As defined in this standard, "microwave ovens" are limited to those manufactured for use in homes, restaurants, food vending, or service establishments, on interstate carriers, and in similar facilities.

(2) "Cavity" means that portion of the microwave oven in which food may be heated, cooked, or dried.

(3) "Door" means the movable barrier which prevents access to the cavity during operation and whose function is to prevent emission of microwave energy from the passage or opening which provides access to the cavity.

(4) "Safety interlock" means a device or system of devices which is intended to prevent generation of microwave energy when access to the cavity is possible.

(5) "Service adjustments or service procedures" mean those servicing methods prescribed by the manufacturer for a specific product model.

(6) "Stirrer" means that feature of a microwave oven which is intended to provide uniform heating of the load by constantly changing the standing wave pattern within the cavity or moving the load.

(7) "External surface" means the outside surface of the cabinet or enclosure provided by the manufacturer as part of the microwave oven, including doors, door handles, latches, and control knobs.

(c) *Requirements*—(1) *Power density limit.* The power density of the microwave radiation emitted by a microwave oven shall not exceed one (1) milliwatt per square centimeter at any point 5 centimeters or more from the external surface of the oven, measured prior to acquisition by a purchaser, and thereafter, 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven.

(2) *Door and safety interlocks.* (i) Microwave ovens shall have a minimum of two operative safety interlocks one of which must be concealed. A concealed safety interlock on a fully assembled microwave oven must not be operable by (*a*) any part of the body, or (*b*) a rod 3 millimeters or greater in diameter and with a useful length of 10 centimeters. A magnetically operated interlock is considered to be concealed only if a test magnet, held in place on the oven by gravity or its own attraction, cannot operate the safety interlock. The test magnet shall have a pull at zero air gap of at least 4.5 kilograms and a pull at 1 centimeter air gap of at least 450 grams when the face of the magnet which is toward the interlock switch when the magnet is in the test position is pulling against one of the large faces of a mild steel armature having dimensions of 80 millimeters by 50 millimeters by 8 millimeters.

(ii) Failure of any single mechanical or electrical component of the microwave oven shall not cause all safety interlocks to be inoperative.

(iii) Service adjustments or service procedures on the microwave oven shall not cause the safety interlocks to become inoperative or the microwave radiation emission to exceed the power density limits of this section as a result of such service adjustments or procedures.

(iv) Insertion of an object into the oven cavity through any opening while the door is closed shall not cause microwave radiation emission from the oven to exceed the applicable power density limits specified in this section.

(v) One (the primary) required safety interlock shall prevent microwave radiation emission in excess of the requirement of paragraph (c)(1) of this section; the other (secondary) required safety interlock shall prevent microwave radiation emission in excess of 5 milliwatts per square centimeter at any point 5 centimeters or more from the external surface of the oven. The two required safety interlocks shall be designated as primary or secondary in the service instructions for the oven.

(vi) A means of monitoring one or both of the required safety interlocks shall be provided which shall cause the oven to become inoperable and remain so until repaired if the required safety interlock(s) should fail to perform required functions as specified in this section. Interlock failures shall not disrupt the monitoring function.

(3) *Measurements and test conditions.* (i) Compliance with the power density limits in this paragraph shall be determined by measurements of microwave power density made with an instrument system which (*a*) reaches 90 percent of its steady-state reading within 3 seconds when the system is subjected to a stepped input signal and which (*b*) has a radiation detector with an effective aperture of 25 square centimeters or less as measured in a plane wave, said aperture having no dimension exceeding 10 centimeters. This aperture shall be determined at the fundamental frequency of the oven being tested for compliance. The instrument system shall be capable of measuring the power density limits of this section with an accuracy of plus 25 percent and minus 20 percent (plus or minus 1 decibel).

(ii) Microwave ovens shall be in compliance with the power density limits if the maximum reading obtained at the location of greatest microwave radiation emission does not exceed the limits specified in this paragraph when the emis-

sion is measured through at least one stirrer cycle. Pursuant to § 1010.13 of this chapter, manufacturers may request alternative test procedures if, as a result of the stirrer characteristics of a microwave oven, such oven is not susceptible to testing by the procedures described in this subdivision.

(iii) Measurements shall be made with the microwave oven operating at its maximum output and containing a load of 275±15 milliliters of tap water initially at 20°±5° centigrade placed within the cavity at the center of the load-carrying surface provided by the manufacturer. The water container shall be a low form 600-milliliter beaker having an inside diameter of approximately 8.5 centimeters and made of an electrically nonconductive material such as glass or plastic.

(iv) Measurements shall be made with the door fully closed as well as with the door fixed in any other position which allows the oven to operate.

(4) *Instructions.* Manufacturers of microwave ovens to which this section is applicable shall provide or cause to be provided:

(i) To servicing dealers and distributors and to others upon request, for each oven model, adequate instructions for service adjustments and service procedures including clear warnings of precautions to be taken to avoid possible exposure to microwave radiation;

(ii) With each oven, adequate instructions for its safe use including clear warnings of precautions to be taken to avoid possible exposure to microwave radiation.

(Sec. 358, 82 Stat. 1177; 42 U.S.C. 263f)

[FR Doc.73-21646 Filed 10-12-73;8:45 am]

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